Saline-Filled Testicular Implant Patient Education Guide
Mentor Urology

Cover Title

Important Information to Remember about Testicular Implants

Table of Contents

Inside

What are my choices?

Saline-filled testicular implants are available from Mentor for males of all ages who have lost or will lose a testicle.

Your doctor and your family members can give you advice about this implant surgery. But, the choice to get a testicular implant is a decision that you must make. This booklet is designed to educate you about saline-filled testicular implants manufactured by Mentor. It's also intended help you make an intelligent, informed decision.

This booklet should not be considered a substitute for medical advice. It is not intended to replace any discussion between you and your doctor. The booklet provides you with a solid foundation for forming questions to ask your doctor about the saline-filled implant procedure.

What factors should be considered when deciding whether to have a testicular implant?

A number of published studies have described the negative psychological effects that can result from the loss or absence of a testicle. Various research studies show that the cosmetic benefits of saline-filled testicular implants lead to emotional benefits and high levels of patient satisfaction.

Saline-filled testicular implants may be an appropriate choice for children with undescended testicles or *torsion* of the testicles. Torsion is an extreme rotation or twisting of one or both testicles that can result in damage that requires removal of the testicle. Adult males also can experience torsion in addition to other traumatic injuries or testicular cancer, all of which may require removal of a testicle.

In cases of undescended testicles, your doctor will attempt to find and remove the undescended testicle. This will prevent the future risk of cancer of the undescended testicle.

Saline-filled testicular implants are not recommended if there is infection within the scrotum or anywhere in the body.

Before choosing to receive a testicular implant, you should speak to your doctor about your long-term expectations, and all the potential risks and complications that can result from the

procedure. It's important to know that a testicular implant is strictly for cosmetic appearances only, and in no way functions like a natural testicle.

Is there an alternative treatment?

Although the testicular prostheses can create or restore a more normal cosmetic appearance of a testes-containing scrotum, the alternative to implant placement is simply no treatment. Not having treatment will require leaving a partially empty or completely empty scrotum.

Another alternative is a procedure called subcapsular orchiectomy which removes the testicle tissue from the capsule. The empty capsule is left in the scrotum. Although this tissue removal provides a smaller scrotal structure, it may be preferable to the alternative of an empty scrotum as described above.

Contraindications

There are several conditions that could increase the risk of injury from testicular implants or make device implantation difficult or impossible. Your doctor will need to consider these conditions when deciding to implant the testicular device. These contraindications may include infection and untreated neoplasm (cancer).

What is a testicular implant? (An unshaded, labeled, line drawing will be placed in this section.)

About the Device

The Mentor saline-filled testicular implant is about the same weight, shape and softness of a normal testicle. It comes in four sizes – extra small, small, medium and large. The implant is made of a molded silicone elastomer shell that is approximately 0.035 inches thick. It is not visible on x-ray.

How the Device Works

The Mentor saline-filled testicular implant is filled by your doctor before surgery. It includes a self-sealing injection site at one end that allows the doctor to fill the device with a sterile saline solution. On the opposite end of the implant is a silicone elastomer tab that enables the doctor to suture and secure the implant into a set position, if this is desired. Once the implant has been filled and sutured into place, the doctor can add more saline for a better cosmetic appearance.

Considerations

You should know that testicular implants, like other medical implant devices, should not be considered lifetime devices. There is the chance, though minimal, that the body could have an

adverse reaction to the implant, or that the implant may either rupture or leak (or both). These will require the implant to be removed (see "What are the potential risks and complications?"). The long-term rates of deflation and re-surgery are currently not known, however a 5-year study is currently being done to assess these possible problems.

Based on the information from the clinical studies of the saline-filled testicular implant, approximately 1 in 30 patients require resurgery within the first year to either remove or adjust the implant.

Testicular implants placed in a small child may need to replaced by a larger implant as the child matures and grows, if the child or his parents wish to maintain a size that closely matches the child's other healthy testicle. In addition, infection, extrusion (when the implant shifts and presses out through the skin) may also require additional surgery.

How will my body react to a testicular implant?

A body's natural response to any implanted object is to reject it. The body's rejection response depends in part on the *biocompatibility* of the materials that make up the implanted device. Biocompatibility is the ability of an object or substance to blend with the body's natural tissues without creating a harmful response. The more biocompatible a material is, the less the body will reject it.

Scientists are continually seeking new materials that are more biocompatible. The most common biocompatible material available today for testicular implants is silicone, which is used in many medical and consumer products.

As a natural reaction to any device placed in the body, scar tissue may form around a testicular implant. This is called a capsule. In some men, the capsule can contract, causing a condition known as *fibrous capsular contracture*. This can result in a hardening of the testicular implant, which may cause discomfort or pain. Fortunately, medical research has shown incidences of fibrous capsular contracture to be low in testicular implant cases.

If I want a testicular implant, what do I do next?

Find a urologist that you are comfortable with and who is able to answer your questions. Make sure that he or she has had experience implanting this device. Prior to scheduling a procedure, be sure to consult with your insurance company to assure that they will cover your testicular implant surgery.

What should I know about the procedure?

If you decide to have a testicular implant procedure, you'll be required to undergo some routine tests a couple weeks before your surgery. Such tests usually include a general physical exam and will include providing blood and urine samples.

There are several factors that may affect your procedure, recovery and results. These factors should be understood and carefully discussed with your doctor prior to the procedure.
Factors to consider before your surgery:

- Overall health
- Healing capabilities (which can be affected by smoking, alcohol and medications)
- Prior scrotal surgeries

Factors to consider after your surgery:

- Infections
- Shifting of the implant
- Scarring from the incision
- Possible hardening of the capsule around the implant

Testicular implant surgery can be performed on an outpatient basis (no overnight stay), or it may require a brief hospital stay. Depending on your case, your surgeon will inform you which approach is best suited for you. Your surgeon also will advise you if you should receive general anesthesia (you'll be asleep) or local anesthesia during your procedure. With a local anesthetic, you'll be awake, but the lower part of your body will be numb throughout the procedure.

Typically, testicular implant procedures are relatively simple and last from 20 to 40 minutes. There are several different accepted surgical approaches that can be used to insert your testicular implant. Your surgeon will discuss with you the method that he or she will use, and why it is the most appropriate choice for your individual case.

It is important to know that implantation of a testicular prosthesis may not be a one-time procedure. Any complications from your surgery may require further procedures.

What will my recovery be like?

You will experience some discomfort during the first 24 to 48 hours after your procedure. Your doctor may or may not decide to prescribe painkillers. You'll probably be instructed to keep your surgical bandages on your scrotum for at least a few days. Most likely you will feel fatigued and your scrotum will be swollen, tender and sensitive to physical contact for some time. However, your ability to urinate should not be affected.

Although every person's recovery time is different, you should be able to resume most of your daily activities within a week to ten days. However, you will have to wait at least a month before resuming strenuous activities. Remember to be patient, and try not to rush your recovery time.

Your doctor will be able to provide you with more specific details about your recovery process, including the amount of time to wait before resuming sex, and he or she may have additional recommendations based on your individual needs. Should any problems occur after your procedure, immediately contact your doctor. This is especially important if you have a high temperature, or if your scrotum becomes excessively swollen (enlarged beyond its normal size), painful, red or inflamed.

It is also important that if you visit another doctor for a different medical matter, you tell that doctor you have a testicular implant to prevent additional and unnecessary surgery. If other doctors are not told of the implant, they may mistake the device for a testicular abnormality and recommend exploratory surgery.

What are the potential risks and complications?

Mentor has developed this booklet to give you general information. It is very important that you carefully read the following risks and complications information, completely understand it, and discuss it with your doctor. The rates of complications listed in this section were obtained from a clinical study of the Saline-Filled Testicular Prosthesis called "the Core Study". This study is described in more detail in Appendix A.

Testicular surgery requires an incision. As with any surgical procedure, there are risks such as infection, delayed wound healing, fluid collection, hematoma formation (a collection of blood inside the body in and around where the incision is made), bleeding and possible reactions from anesthesia. These complications are uncommon.

Small areas of fluid collection and small hematomas will be absorbed by your body.

In addition to these known risks, there are unanswered questions about silicone implants, which mostly apply to silicone gel-filled breast implants. You will be receiving saline-filled implants that contain only salt water. Certain risks that may be associated with silicone gel will not occur with saline-filled implants. However, since both types of implants have a silicone rubber envelope, they may be associated with certain specific risks and complications.

The known or potential risks of saline-filled testicular implants or the implant surgery are as follows:

Calcium Deposits: Any surgery or injury to the testicle can produce small spots of calcium in the testicle(s) that can be seen on x-rays. These deposits may not occur until years after implant surgery. They are benign (non-cancerous) and cause no problems but must be differentiated from the calcium that is often seen in testicular cancers. A biopsy may be necessary to make this distinction.

Deflation/Rupture of the Implant: Causes of rupture and/or deflation of implants include, but are not limited to, the following events (this was reported in 0.7% of the Core Study patients):

- damage to implant prior or during surgery such as abrasion to the shell, over-filling the implant , or from surgical instruments;
- postoperative trauma that may occur during activities such as bicycle riding, contact sports, manual massage, intimate physical contact, and any other activity that may put stress on the groin area; or
- damage from unknown causes.

Discomfort/Pain: An uncomfortable feeling around the area of operation that is normally associated with surgery, and usually goes away. The length of time of this discomfort or pain should be discussed with your doctor or surgeon (discomfort was reported in 4.0%, and pain was reported in 5.4% of the Core Study patients).

Displacement/Migration/Shifting of the Implant: The movement of the device from its originally implanted position. This occurred in approximately 2% of the patients in the clinical study.

Dissatisfaction with Cosmetic Results: Incorrect implant size or migration (movement of implant from original position) of implants may interfere with a satisfactory cosmetic result.

Extrusion of Implant/Interruption of Wound Healing: Extrusion is when the implant shifts and presses out through the skin (this was reported in 2.0% of the Core Study patients). In addition, skin damage, sloughing (shedding of dead skin), or wound separation may result from:

- tight pull of skin over the implant,
- trauma to the skin during the surgery, or
- not enough tissue to cover the implant; this may block the blood circulation.

Fluid Collection: A natural process where excessive fluid accumulates around the implant after, and as a result, of your surgery (this was reported in 0.7% of the Core Study patients).

Hardening of Testicular Implant: This can occur as a result of the body's natural reaction to a device placed in the body. It is caused by the formation and contraction of scar tissue around the implant. The implant may be difficult to remove if the degree of scar tissue is significant.

Hemorrhage: Bleeding due to a cut or scratch. This is related to the surgical procedure.

Hematoma: Hematomas are a collection of blood, usually a clot, that occurs in tissue due to a break in a blood vessel. Large hematomas, manifested by enlargement, tenderness and discoloration of tissue may, if untreated, lead to extrusion of the implant (this was reported in 1.3% of the Core Study patients).

Infection: Infection, manifested by swelling, tenderness, pain and fever, may appear in the immediate postoperative period or at any time after insertion of the implant. If an infection does not clear up promptly with proper treatment, your surgeon may have to remove your implant.

Irritation: Some materials in this device have been shown, during animal studies, to be irritants. It is possible that you may experience some irritation from this testicular implant.

Keloid: A thick scar that results from excessive growth of fibrous tissue (this was reported in 1.3% of the Core Study patients).

Necrosis: Necrosis is the death of tissue cells and may lead to implant extrusion.

Numbness: A lack of feeling or sensation in the lower part of the body caused by the surgery and not the presence of the implant (this was reported in 0.7% of the Core Study patients).

Overfilling of Implants: When more than the recommended volume of saline is injected into the implant.

Scarring: A mark left by healing of damaged tissue.

Sepsis: The spread of bacteria from the original site of infection.

Swollen Lymph Nodes: Lymph nodes are the normal way the body removes certain kinds of waste from its system. When this process takes place, the lymph nodes can appear swollen. As the nodes drain, the swelling will eventually go away signaling that the waste (dead cells mixed with water) is being removed from the body.

Thrombosis: The formation or development of a blood clot within a blood vein. This is related to the surgical procedure.

Other: The long-term effects of this device have not been clearly established in animal studies and therefore are not fully known.

The theoretical risks of silicone are:

Allergies: The body's natural reaction to the presence of material not normally present in the body. This can take to form of sneezing, coughing, itching, skin rashes, etc.

Biocompatibility: Reports in the medical literature suggest that biocompatibility responses may be affected by different biomedical materials, such as silicone.

Birth Defects: Preliminary animal studies show no evidence that silicone testicular implants would cause birth defects to any future children parented by a recipient of this device. However, to rule out that possibility for humans, further scientific studies are necessary to show whether or not testicular implants are associated with birth defects.

Cancer: There is presently no established scientific evidence that links silicone testicular or breast implants with cancer. However, the possibility cannot be ruled out.

Connective Tissue Disorders: There have been reports describing an association between certain silicone-based products and certain connective tissue disorders. These are a group of disorders in which the body reacts to its own tissue as though it was foreign material. These disorders can cause long-term, serious, disabling health problems. Symptoms may include pain and swelling of joints, tightness, redness or swelling of the skin, swollen glands or lymph nodes, unusual and unexplained fatigue, swelling of the hands and feet, and unusual hair loss. Generally, people who have these relatively rare connective tissue disorders experience a combination of these and other symptoms.

Some cases of these disorders have been reported in women with breast implants. Some of these women have reported a reduction in symptoms after their implants were removed. Manufacturers are sponsoring large-scale scientific studies to explore whether a possible link exists between silicone breast implants and connective tissue disorders. To date, however, there is no evidence that these disorders occur more often in women who have silicone breast implants when matched to women of similar ages.

Degradation and Particle Shedding: The medical literature suggests that degradation and particle shedding (harmless, microscopic (very small), silicone particles dislodged from the surface of the implant due to rubbing) of a silicone elastomer shell, such as that used for the saline-filled testicular implant, may occur in the capsule that normally develops around the implant and in draining lymph nodes. Further research is being undertaken to determine the effects of degradation and the possibility of toxicity.

Neurological Symptoms: There have been some reports of patients experiencing neurological symptoms at variable times after breast implant surgery. Some of the complaints have involved difficulties with vision, sensation, muscle strength, walking, and balance. These reports do not prove a link between the implants and neurological problems.

Your doctor will discuss any additional information about the risks of saline-filled testicular implants and your surgical procedure. Testicular implants are not considered to be lifetime implants. The expected life of the implant is unknown. You are encouraged to read the Product Insert Data Sheet, which will be provided to you by your doctor.

Appendix A

Mentor Clinical Study Results

Saline-filled testicular implants are new medical devices. To assess the safety and effectiveness of this device, a multicenter clinical trial (the "Core Study") was performed. Additionally, a separate study (the "Adjunct Study") was performed to collect additional safety data while the Core Study was ongoing. One hundred and forty nine (149) subjects were treated in the Core Study, and 209 subjects were treated in the Adjunct Study. Both studies treated children and adult patients.

Safety

The main complications noted in these studies were as follows:

Pain and/or discomfort occurred in approximately 10% of patients.

Temporary swelling at the implant site in approximately 3% of patients.

Extrusion of the implant in approximately 2% of the patients.

Infection at the implant site in approximately 1% of patients.

Displacement/migration of the implant in approximately 2% of patients.

Approximately 1 in 30 patients required resurgery within 1 year after device implantation in these studies, usually to remove the implant. The most common reason for implant removal was extrusion of the implant.

Effectiveness

The effectiveness of the implant is based on the following results of the Core Study:

Physician measurements documented that the implanted device adequately mimics the size of the natural testicle.

The cosmetic appearance and firmness of the implanted device was rated as normal by physicians.

Using standardized questionnaires, patients recorded high levels of satisfaction with the implant, as well as increased levels of how they viewed their body in sexual activities. Additionally, there was no decline in either self-esteem or body-esteem, as assessed using the Rosenberg Self-Esteem Scale and the Body Esteem Scale.